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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/581,718  | 06/22/2006  | Denis Claude Roy     | 1032256-000056      | 8573             |
| 34263 7590 06/01/2010<br>O'Melveny & Myers LLP<br>IP&T Calendar Department L.A-13-A7<br>400 South Hope Street<br>Los Angeles, CA 90071-2899 |             |                      |                     |                  |
| EXAMINER<br>JUDES, AMYE   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1644  |             |                      |                     |                  |
| NOTIFICATION DATE   |             | DELIVERY MODE        |                     |                  |
| 06/01/2010  |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipcalendardept@omm.com  
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### Office Action Summary

**Application No.**

10/581,718

**Applicant(s)**

ROY ET AL.

**Examiner**

AMY E. JUEDES

**Art Unit**

1644

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-83 is/are pending in the application.
- 4a) Of the above claim(s) 53-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-52 and 82-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 5/10/10 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/13/10 has been entered.

Claims 49 and 83 have been amended.

Claims 49-83 are pending.

Claims 53-81 stand withdrawn from further consideration pursuant to 37 CFR 1.14209 as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 49-52 and 82-83 are under examination.

2. The rejection of the claims under 35 U.S.C. 102 as being anticipated by Brasseur et al and Roy et al., the rejection under 35 U.S.C. 103,, and the rejection for obviousness type double patenting are withdrawn in view of Applicant's amendment to recite a composition comprising "dead cell material derived from PDT treatment of autologous autoreactive peripheral blood cells".

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 49-52 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/24824 (of record).

WO 01/24824 teaches a composition comprising an autologous cell vaccine for treatment of autoimmune disease in a patient, said composition comprising PDT treated peripheral blood cells (see pages 11-12 and 18-19, in particular). WO 01/24824 teaches that said blood cells comprise autoreactive cells (see page 18, in particular). WO 01/24824 teaches a photactivatable compound of formula I of the instant application. WO 01/24824 teaches activating said compound with light of a wavelength of around 512 nm (see pages 10-11 and 21, in particular). WO 01/24824 teaches that the compound/light treatment of the cell compositions results in destruction (i.e. death) of cells in the composition (see page 10 in particular). WO 01/24824 teaches that the vaccine can induce immunomodulation through enhanced presentation of antigens from the apoptotic/dead immunoreactive (i.e. autoreactive) cells in the composition (see page 19, in particular).

Applicant's arguments filed 1/13/10 have been fully considered, but they are not persuasive.

Applicant argues that that WO 01/24824 teaches PDT treated alloreactive T cells, but not autoreactive peripheral blood cells.

WO 01/24824 teaches PDT treated alloreactive, as well as PDT treated autoreactive peripheral blood cells, as noted above.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49-52 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/24824, in view of Gollnick et al., March 2003 (both of record).

The teachings of WO 01/24824 are described above.

WO 01/24824 does not teach a vaccine consisting of a supernatant of the PDT treated cells.

Gollnick et al. teach a lysate of PDT treated cells can be used as an immunologic vaccine to induce an immune response against antigens from the cells (see page 1604, in particular). Gollnick et al. teach producing the cell lysate by treating the cells with photoforin (i.e. a photoactivatable compound) activating the cells with light (see page 1604, in particular), and separating and collecting the cell supernatant.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use an immunologic vaccine consisting of the supernatant of PDT treated cells, as taught by Gollnick et al., using the PDT treated autoreactive peripheral blood cells of WO 01/24824. The ordinary artisan would have been motivated to do so, and have a reasonable expectation of success, since Gollnick et al. teach that said supernatants act as potent immunologic vaccines, and WO 01/24824 teaches that the presentation of antigens from autoreactive PDT treated cell vaccine is effective for treatment of autoimmune disorders.

6. Claim 49-52 and 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/24824 in view of Lambert et al., 2001.

The teachings of WO 01/24824 are discussed above.

WO 01/24824 does not teach the immunologic vaccine further comprising non-PDT treated APCs.

Lambert et al. teach that dendritic cells loaded with apoptotic or lysed cells induce a more potent immune response than the cells or cellular antigen alone.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a non-PDT treated dendritic cell, as taught by Lambert et al., in the immunologic vaccine comprising dead/apoptotic cellular material as taught by WO 01/24824. One of ordinary skill in the art at the time the invention was made would have been motivated to include a dendritic cell in the immunologic vaccine in order to enhance the presentation of the dead cellular material of the vaccine and induce an enhanced immune response to the cellular material.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 1644

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